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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/342,314	06/29/1999	MICHAEL J. YELLIN	C014CIP/DIV2	6376

7590 09/30/2002

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EXAMINER
GAMBEL, PHILLIP

ART UNIT	PAPER NUMBER
1644	19

DATE MAILED: 09/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

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NOTIFICATION OF DEFECTIVE NOTICE OF APPEAL OR DEFECTIVE BRIEF

1. ☐ The Notice of Appeal filed _____ is:

A. ☐ Not acceptable for reason(s) that:

(1) ☐ The Appeal fee required by 35 U.S.C. 41 (a)(6) and 37 CFR 1.17(e) was not submitted with the Notice of Appeal.

(2) ☐ The submitted fee of $ _____ is insufficient. The appeal fee required by 37 CFR 1.17(e) is $ _____.

(3) ☐ The Notice of Appeal was not timely filed.

(4) ☐ The Appeal fee received on _____ was not timely filed.

(5) ☐ The Appeal is not in compliance with 37 CFR 1.191 in that the claims have not been finally or twice rejected.

(6) ☐ A Notice of Allowability was mailed by the Office on _____.

B. ☐ Defective and should be corrected as indicated. Applicant is given a TIME LIMIT of ONE MONTH from the date of this letter OR the TIME REMAINING IN THE RESPONSE PERIOD OF THE LAST OFFICE ACTION, whichever is longer, to complete the appeal. NO EXTENSION OF THIS ONE MONTH PERIOD MAY BE GRANTED UNDER 37 CFR 1.136(a) or (b) BUT THE PERIOD FOR RESPONSE SET IN THE LAST ACTION MAY POSSIBLY BE EXTENDED. If the appeal is not timely completed, the application will be abandoned.

(1) ☐ The Notice of Appeal is not signed.

(2) ☐ Identification of the appealed claim or claims is required under 37 CFR 1.191 (b).

2. ☐ The Brief filed _____ is NOT acceptable for the reason(s) indicated below.

The Appeal in this application will be dismissed unless the applicant makes the Brief acceptable. Extensions of time may be obtained under 37 CFR 1.136(a).

APPLICANT'S REPRESENTATIVE INDICATED APPLICATION WOULD BE ABANDONED IN FAVOR OF A CONTINUATION (9/27/01)

A. ☐ The Brief and/or Brief fee is untimely. See 37 CFR 1.192.

B. ☐ The requisite fee which must accompany the Brief has been omitted. See 37 CFR 1.17(f).

C. ☐ The submitted Brief fee of _____ is not the proper amount. The Brief fee required by 37 CFR 1.17(f) is _____.

3. ☒ The Appeal in this application is DISMISSED because

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A. ☐ The fee for filing the Brief as required under 37 CFR 1.17(f) was not submitted or timely submitted and the period for obtaining an extension of time to file the brief under 37 CFR 1.136 has expired.

B. ☒ The Brief was not filed, or was not timely filed and the period for obtaining an extension of time to file the brief under 37 CFR 1.136 has expired.

4. ☒ As the result of the dismissal in "3" above, this application:

A. ☒ is abandoned since there are no allowed claims.

B. ☐ is being returned to the examiner for disposition since it contains allowed claims. Prosecution on the merits is CLOSED.

DETAILED ACTION

1. Applicant's amendment, filed 8/6/01 (Paper No. 13), has been entered.
Claims 102, 109-111 and 128-129 have been canceled. Claims 2-102 have been canceled previously.
Claims 1, 103, 104, 110, 111, 128 and 129 have been amended.
Claims 130-131 have been added.

Claims 1, 103-108, 112-127 and 130-131 are pending and being acted upon presently.

2. The text of those sections of Title 35 USC not included in this Action can be found in a prior Action.
This Office Action will be in response to applicant's arguments, filed 8/6/01 (Paper No. 13).
The rejections of record can be found in the previous Office Action (Paper No. 11).

3. The previous rejections under 35 U.S.C. § 112, first and second paragraphs, enablement and written description have been withdrawn in view of applicant's canceled claims, filed 8/6/01 (Paper No. 13).

4. Claims 1 and 103-105, 109, 112-117 and newly added claims 130-131 are rejected under 35 U.S.C. § 102(e) as being anticipated by Wilson et al. (U.S. Patent No. 5,652,224) essentially for the same reasons of record set forth in Paper No. 11.

Claims 1, 103-108, 112-127 and newly submitted claims 130-131 are rejected under 35 U.S.C. § 103 as being unpatentable over Wilson et al. (U.S. Patent No. 5,652,224) in view of art known methods of generating modified antibodies of interest, as acknowledged by applicant on pages 13-15 of the instant specification and in view of Lederman et al. (WO 93/09812; 1449), essentially for the same reasons of record set forth in Paper No. 11.

Applicant's arguments, filed 8/6/01 (Paper No. 13), have been fully considered but are not found convincing essentially for the reasons of record set forth in Paper No. 11.

Applicant acknowledges that Wilson et al. teach the use of gene therapy vectors in combination with immunomodulators such as anti-CD40L antibodies to treat various disorders including atherosclerosis.

Applicant asserts that the teachings of Wilson et al. are directed to the co-administration of immune modulators such as CD40L-specific antibodies in order to inhibit immune responses, which is clearly limited to the prevention of immune responses which develop as a result of delivery of the gene therapy vector.

In contrast to the teachings of Wilson et al.; applicant argues that the instant claims are directed to the treatment of atherosclerosis with an antibody that inhibits the interactions between the CD40L and CD40, thereby preventing the activation of CD40-bearing cells, which play a role in atherosclerosis.

Applicant asserts that the instant methods are effective irrespective of whether the patient suffers from an underlying metabolic disorder.

Applicant argues that Wilson et al. does not teach methods of treating atherosclerosis by administering CD40L-specific antibodies in order to inhibit the interaction between CD40L and CD40, thereby preventing the activation of CD40-bearing cells.

In addition, applicant argues that neither White et al. nor Lederman et al. teach specific dosages that inhibit the interaction between CD40L and CD40 bearing cells recited in the instant claims.

In response to applicant's argument's in conjunction with In re Ochiai that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. In re McLaughlin , 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). See MPEP 2145.

Also, it is noted that obviousness can be established for achieving the claimed product for different reasons and the prior art/examiner does not need to know all of the properties of the claimed invention In re Dillon, 16 USPQ2d 1897 (Fed. Cir. 1990); however there must be some suggestion or motivation. Therefore, the reason or motivation to combine may often suggest doing what the inventor has done, but for a different purpose or to solve a different problem than that asserted by the inventor. See MPEP 2144.

As pointed out previously, it is noted that the claimed methods recite "comprising" which leaves the claim open for the inclusion of unspecified ingredients even in major amounts. See MPEP 2111.03.

With respect to inherency as well as obviousness; it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure, given the open "comprising" language.

As acknowledged by applicant; Wilson et al. does teach the use of gene therapy vectors in combination with immunomodulators such as anti-CD40L antibodies (column 17, paragraph 4) to treat various disorders including atherosclerosis (see entire document, including Background of the Invention, and Detailed Description of the Invention).

In contrast to applicant's recitation of comprising; applicant is invited to consider amending the claims to recite "consisting essentially of" and distinguishing the claims from the prior art according to the following. See MPEP 2111.03.

The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not *materially* affect the *basic* and *novel* characteristic(s)" of the claimed invention. *In re Herz* , 537 F.2d 549, 551 - 52, 190 USPQ 461, 463 (CCPA 1976)(emphasis in original)(Prior art hydraulic fluid required a dispersant which appellants argued was excluded from claims limited to a functional fluid "consisting essentially of" certain components. In finding the claims did not exclude the prior art dispersant, the court noted that appellants' specification indicated the claimed composition can contain any well - known additive such as a dispersant, and there was no evidence that the presence of a dispersant would materially affect the basic and novel characteristic of the claimed invention. The prior art composition had the same basic and novel characteristic (increased oxidation resistance) as well as additional enhanced detergent and dispersant characteristics.). See also *Atlas Powder Co.* v. *E.I. duPont de Nemours & Co.* , 750 F.2d 1569, 224 USPQ 409 (Fed. Cir. 1984); *In re Janakirama - Rao*, 317 F.2d 951, 137 USPQ 893 (CCPA 1963); *Water Technologies Corp.* v. *Calco, Ltd* ., 850 F.2d 660, 7 USPQ2d 1097 (Fed. Cir. 1988). When an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also *Ex parte Hoffman*, 12 USPQ2d 1061, 1063 - 64 (Bd. Pat. App. & Inter. 1989)("Although `consisting essentially of' is typically used and defined in the context of compositions of matter, we find nothing intrinsically wrong with the use of such language as a modifier of method steps . . . [rendering] the claim open only for the inclusion of steps which do not materially affect the basic and novel characteristics of the claimed method. To determine the steps included versus excluded the claim must be read in light of the specification . . . . [I]t is an applicant's burden to establish that a step practiced in a prior art method is excluded from his claims by `consisting essentially of' language.").

Also with respect to inherency; see Ex parte Novitski 26 USPQ 1389 (BPAI 1993); Mehl/Biophile International Corp. V. Milgraum, 52 USPQ2d 1303 (Fed. Cir. 1999); Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999); and Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001).

Newly discovered results of known processes directed to the same purpose are not patentable because such results are inherent. See Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999) and Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001).

Given the teachings that the immunomodulator anti-CD40L antibodies would be beneficial in the treatment of atherosclerosis and the teachings that 5C8-/CD40L-specific antibodies affect a number of cell interactions; the claimed effects on transmigration, blood vessels, endothelial cells and smooth muscle cells would have been expected given the ability to inhibit CD40L-mediated responses including the inhibition of atherosclerosis.

Also, as pointed out previously, the claimed dosages and routes of administration were known and practiced at the time the invention was made and/or would have been encompassed in providing for sufficient therapeutic intervention depending on the patient's needs at the time the invention was made.

One of ordinary skill in the art at the time the invention was made would have been motivated to select the ability of CD40L-specific antibodies in combination with a gene therapy to inhibit atherosclerosis. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicant's arguments are not found persuasive.

5. No claim is allowed.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Phillip Gambel

Phillip Gambel, PhD.
Primary Examiner
Technology Center 1600
October 18, 2001